

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Dennis O'Brien et al. Confirmation No.: 2053  
Serial No.: 10/725,178 Examiner: Diane D. Yabut  
Filed: December 1, 2003 Group Art Unit: 3734  
Docket No.: S63.2-13172-US01 (1001.2174101) Customer No.: 28075  
Title: CUTTING BALLOON HAVING SHEATHED INCISING ELEMENTS

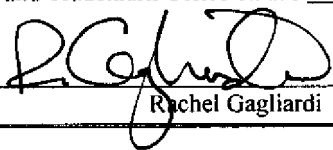
**REPLY BRIEF UNDER 37 CFR§ 41.41**

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The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 27th day of August 2008.

By \_\_\_\_\_



Rachel Gagliardi

Dear Sir:

Appellants have carefully reviewed the Examiner's Answer mailed June 27, 2008.  
Appellants note the New Grounds of Rejection made on page 3.

**Response to New Grounds of Rejection**

On page 3 of the Examiner's Answer, two New Grounds of Rejection were presented. The rejection of claim 5 under § 103(a) has been withdrawn and claim 5 has been added to the rejection under §102(b) as being anticipated by Barath. In the rejection of claim 9 the Shiber reference is no longer being used. The Shiber reference is thus not used for any rejection. Appellant's response to the new grounds of rejection are incorporated into the following arguments.

Argument

Claims 1, 2, 5, 8, and 10 are patentable over Barath (US 5,616,149). Independent claim 1 recites, in part:

a radially compressible sheath mounted on said balloon along the length of said incising element and extending radially from said balloon and beyond said surface feature when said balloon is in the first configuration to protect said surface feature during transit to the treatment site, said sheath being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated into the second configuration.

Emphasis added. Barath does not appear to teach the identical invention. MPEP 2131 states:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Emphasis added. Appellants submit that Barath does not teach the identical invention in the complete detail as recited in the independent claim and thus cannot be deemed to anticipate the claims. In particular, Barath does not appear to teach a radially compressible sheath positioned for radial compression between tissue and the balloon to expose the surface feature for tissue incision. Barath appears to teach sheath 17 with longitudinal grooves 18 that "open up" or expand laterally when the balloon is inflated. This is illustrated in the difference in the size of grooves 18 between Figure 12 (unexpanded balloon), and Figure 13 (expanded balloon). The grooves 18 are clearly expanded laterally as the balloon expands, allowing the cutting edges 6 to be exposed. Barath appears to teach expansion of the balloon causing exposure of the cutting edges. The structure of Barath is thus not identical to the claimed structure.

In the Response to Arguments section, on page 7 of the Examiner's Answer, the Examiner asserts that in Figures 12-13 of Barath, the sheath 17 is shown being positioned for radial compression between tissue 7 and balloon 2 while also exposing the surface feature 6. The Examiner also asserts that radial compression of sheath 17 may be achieved during

inflation of the balloon, wherein the sheath may be pressed and held between the tissue and the balloon, and therefore the device of Barath reads on this limitation. Appellants submit that whether a prior art device may be modified to achieve a claimed device is not a proper basis for an anticipation rejection. As stated above, anticipation requires a reference teach the identical invention in as complete detail as in the claim. Figure 13 of Barath shows the device with an expanded balloon, and does not show sheath 17 “pressed and held between the tissue and the balloon” as asserted by the Examiner. On the contrary, Figure 13 shows sheath 17 spaced from the tissue 7, while the cutting edges 6 contact the tissue 7. Barath specifically teaches that “grooves (18) of the protective sheath (17) open up allowing the cutting edges (6) to penetrate into the vessel wall (7, 8) producing cuts with sharp margins (11).” See column 5, lines 31-34. In view of this specific teaching and the figures of Barath, one of ordinary skill in the art would interpret Barath as having a sheath with grooves that open laterally to expose the cutting edges. Appellants submit that there is no teaching in Barath of a structure that is radially compressible between tissue and the balloon to expose a cutting edge. Barath thus fails to teach the identical structure as recited in the independent claim.

The Examiner asserts that while the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Appellants submit that the claim terms asserted are actually recited in the claims and not merely read into the claims from the specification. The Examiner also asserts, on page 7 of the Examiner’s Answer, “the features upon which the appellant relies (i.e., radial compression of the sheath causing exposure of the cutting edge) are not recited in the rejected claim(s).” Appellants respectfully disagree. Independent claim 1 recites in part, “sheath being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated”; emphasis added. The claim thus does recite the sheath positioned for radial compression to expose the surface feature. MPEP 2111 states:

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." >The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:

The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon

giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1).

415 F.3d at 1316, 75 USPQ2d at 1329. See also *< In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000).

...

The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999)

Emphasis added. Appellants submit that the Examiner's interpretation of the claims is inconsistent with the specification and inconsistent with the interpretation reached by one of ordinary skill in the art in light of the specification.

Additionally, if the Examiner is considering the specific elements recited in the claims to be inherent in Barath, Applicants submit that there is no basis for such an interpretation.

MPEP 2112 IV. states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient!'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)...

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the

applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

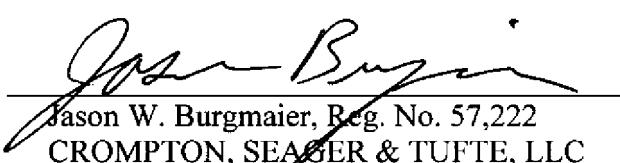
(Emphasis added). Applicants submit that the claimed features, in particular the radially compressible sheath, are not necessarily present in Barath. It appears the Examiner is asserting that the claimed elements may be achieved by modifying Barath, which is not a proper basis for an anticipation rejection.

Regarding claim 4, the Examiner asserts, on page 7 of the Examiner's Answer, that the sheath 17 of Barath covers the entire balloon and acts as a unit with the balloon during inflation and deflation and therefore is considered to be attached, albeit indirectly, to the mounting pad 13. Appellants respectfully disagree. As discussed above, in order to be considered an inherent property, a characteristic must necessarily flow from the teachings in the prior art. Appellants submit that Barath does not provide such teachings and thus cannot be seen to anticipate the device of claim 4.

Claims 11-14 are patentable over Barath. Claims 3, 4, and 9 are patentable over Barath in view of Vigil et al. For at least the reasons set forth above Barath fails to teach the basic elements of independent claim 1, from which claims 3, 4, 9, and 11-14 depend. Vigil et al. do not appear to teach or suggest what Barath lacks, thus any combination of Barath and Vigil et al. also fails to teach or suggest the elements of independent claim 1 or the claims dependent thereon. Reconsideration and withdrawal of all rejections are respectfully requested.

Respectfully submitted,  
Dennis O'Brien et al.  
By their attorney,

Date: Aug 27, 2008

  
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